

Application No.: 09/843,819

Docket No.: OKA-0027

REMARKS

This is a full and timely response to the Office Action mailed November 24, 2003.

By this Amendment, claims 1-3 has been amended to more particularly define the present invention. Support for the claim amendments can be found variously throughout the specification, see for example, page 2, line 16, to page 3, line 2. Claims 1-11 are pending in this application.

In view of this Amendment, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Rejections under 35 U.S.C. §112

Claims 1-12 are rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Applicant respectfully traverses this rejection.

However, in order to expedite prosecution, Applicant has amended claims 1 and 3 to address the Examiner's concerns. Specifically, claim 1 has been amended to replace the term "nucleic acid inclusion body" with "a cellular or intracellular level body comprising nucleic acids." Such an amendment is supported by the disclosure provided on page 2, line 16, to page 3, line 2, of the specification. The meaning of "nucleic acid inclusion body" as used in the present specification is any body, both on the cellular and intracellular level, which comprises nucleic acids. Thus, to clarify claim 1 while keeping the scope of such a claim element (i.e. *nucleic acid inclusion body*) the same, Applicant has amended claim 1 to recite "... wherein a cellular or intracellular level body comprising nucleic acids from a living body-derived sample itself or the living body-derived sample itself is added to the amplification reaction solution".

In addition, Applicant has amended claim 3 to remove the term "and/or" while maintaining the scope of the claim. Claim 3 now reads as "... wherein said amplifying step comprises at least one of adjusting a pH value of the amplification reaction solution to 8.4 or higher if the reaction solution is about 25 °C, and adjusting a pH value of the amplification reaction solution to 7.4 or higher if the reaction solution is about 70 °C". The scope of the new claim language should be the same as "and/or" which means that the adjusting pH steps at about 25 °C and 70 °C can both occur or individually occur during the amplifying step.

Thus, withdrawal of this rejection is respectfully requested.

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Rejections under 35 U.S.C. §103

Claims 1-9 and 11 are rejected under 35 U.S.C. §103(a) as being obvious over Ivanov et al. (U.S. Patent 6,183,998). Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness, the cited reference must teach or suggest all of the claim limitations (see §2142 of the Manual of Patent Examining Procedure). Here, in this case, Ivanov et al. fail to teach or suggest the limitation "... wherein a cellular or intracellular level body comprising nucleic acids from a living body-derived sample itself or the living body-derived sample itself is added to the amplification reaction solution".

The term "itself" is specifically defined on page 8, line 16, to page 9, line 1, of the specification. It states that

"... the term "itself" means that no special pretreatment is required. In the concrete, no following pretreatment is required; the nucleic acid inclusion body is decomposed using an enzyme, a surfactant, a chaotropic agent, or the like, and then nucleic acids are extracted from the decomposed product of the nucleic acid inclusion body using phenol, phenol/chloroform or the like. Further, pretreatment using an ion-exchange resin, a glass filter, glass beads, a reagent having an effect of agglutinating proteins, or the like is not required in the step of the nucleic acid extraction"

In other words, the present invention is directed to a method for synthesis of nucleic acids to directly amplify an intended nucleic acid in a living body-derived sample without purification steps (see Abstract of the present disclosure). As the above definition discloses, the cellular or intracellular level body comprising nucleic acids from a living body-derived sample itself (i.e. a cell itself, a fungus itself, a bacterium itself, or a virus itself) or the living body-derived sample itself is added to the amplification reaction solution and directly amplified. No purification of the nucleic acid is required.

In contrast, Ivanov et al. teach the extraction and purification of nucleic acid prior to amplification. In the examples of Ivanov et al. (see examples 7 and 8, columns 11-13, and example 15, columns 16-18), Ivanov et al. clearly disclose that human genomic DNA from human whole blood and RNA from HeLa cells are extracted and purified using commercial kits (QIAamp® Blood Kit and RNasy® Maxi Kit from Qiagen).

Thus, since Ivanov et al. fail to teach or suggest all the claim limitations (i.e. *itself*), this rejection cannot be sustained and should be withdrawn.

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Claims 10 is rejected under 35 U.S.C. §103(a) as being obvious over Ivanov et al. (U.S. Patent 6,183,998) in view of Yamada et al. (U.S. Patent 5,369,096) or Kelly et al. (U.S. Patent 4,978,757) or Holliger et al. (U.S. Patent 4,820,309) or Ukachi et al. (U.S. Patent 4,683,280) or Endo et al. (U.S. Patent 4,368,314) or Taniguchi et al. (U.S. Patent 6,054,501). Applicant respectfully traverses this rejection. Since the deficiency in Ivanov et al. (i.e. *directly amplifying an intended nucleic acid in a living body-derived sample without purification steps*) is not cured by the teaching and suggestions of the other cited references, this rejection cannot be sustained for the same reasons as noted above, and should be withdrawn.

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CONCLUSION

For the foregoing reasons, all the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

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Respectfully submitted,

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